Intracranial registration in patients with refractory epilepsy, an integrative analysis of brain signals in response to sensory stimuli

Published: 03-09-2014 Last updated: 20-04-2024

To identify neuronal activation patterns in response to cognitive stimuli

Ethical review Approved WMO **Status** Recruiting

Health condition type Seizures (incl subtypes) **Study type** Observational invasive

Summary

ID

NL-OMON53069

Source

ToetsingOnline

Brief title

Cognitive mapping by intracranial registration

Condition

Seizures (incl subtypes)

Synonym

Epilepsy - Convulsions

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cognitive mapping, Grid, High Frequency Activity

Outcome measures

Primary outcome

The main study parameter will be the topographic characterization of the neural activity during the processing of different sensory stimuli and the performance of attention as well as short-term memory tasks. The neural activity will be measured by ECoG and by functional magnetic resonance imaging (fMRI)

Secondary outcome

N.A.

Study description

Background summary

Cognitive stimuli processing is extremely important for humans. Neuronal activation patterns offer insight into cognitive processes. Most non-invasive methods have disadvantages of a limited temporal (fMRI) or spatial resolution (surface EEG). Registration with an intracranial grid electrode (ECoG) can overcome this problem. A combination of ECoG with fMRI can increase our understanding of cognitive processing in healthy controls and patients with epilepsy.

Study objective

To identify neuronal activation patterns in response to cognitive stimuli

Study design

Observational study

Study burden and risks

Participation will imply a test with repetitive stimulation of one of the

sensory modalities (vision, hearing etc.). For hearing: they listen to music, or phonemes or words passively, are will be asked to attend to certain characteristics in the stimuli. For vision: they will read letters or words and are asked to remember them and to recall them afterward. The test is harmless. The grid electrode will not be left longer in situ than clinically necessary. The fMRI at 7T (for patients and controls) carries no risks, though several precautions are taken.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

Medically refractory epilepsy Diagnostic workup up till that moment has not led to decline the patient for resective epilepsy surgery

3 - Intracranial registration in patients with refractory epilepsy, an integrative ... 29-05-2025

A suspected (neo-)cortical seizure focus at the surface of the brain Planned implantation of intracranial electrodes Incapacitating epilepsy or seizures (no absolute minimal frequency) Minimum age 18 years

Exclusion criteria

For patients

- Patients with (co-existent) psychogenic, non-epileptic attacks, or low IQ (below 70).
- (post-ictal) psychosis during the registration period will lead to exclusion from the research., For both patients as well as for controls:
- 1. Head injury with intracranial abnormalities (cerebral contusion)
- 2. Stroke (hemorrhagic or ischemic)
- 3. Metallic prostheses or pacemaker in the subject*s body or other contra indications for MRI. , For the healthy subjects only:
- 1. Any neurological or psychiatric disease
- 2. Use of medication affecting the central nervous system

Study design

Design

Study type: Observational invasive

Intervention model: Other

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruiting
Start date (anticipated): 03-03-2015

Enrollment: 60

Type: Actual

Ethics review

Approved WMO

Date: 03-09-2014

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit

Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date: 20-03-2019

Application type: Amendment

Review commission: METC academisch ziekenhuis Maastricht/Universiteit

Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register ID

CCMO NL47496.068.14